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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/027,248

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Gregory P. Kushla

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09/24/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,248

Applicant(s)

KUSHLA ET AL.

Examiner

Susan Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Receipt is acknowledged of applicant's Extension of Tim filed 06/14/02, and Preliminary Amendment filed 02/20/02.

Claim Objections

Claim 8 is objected to because of the following informality:

It appears that the punctuation “;” in claim 8 should read “.”. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,348,216 ('216). Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '216 claims a pharmaceutical composition comprising ibuprofen and narcotic analgesic in a single dosage form including colloidal silicon

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dioxide, filler, disintegrant, binder, starch and lubricant. All of which are found through out claims 1-34 of the '216 patent. Therefore, those of ordinary skill would expect a similar dosage form from the use of the instant invention given the claims of '216.

There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of '216, which set out a similar pharmaceutical composition as claimed herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in the use of the phrase "extra granule material". It is unclear what can be included in the "extra granule material", as well as the differences between the "granule" and the "extra granule"? Clarification is requested.

The examiner is confused from the wording of claim 4 beginning at "wherein the tablet comprises a compressed blend of a granule and extra granule material wherein the granule compress at least ...and the weight of the extra granule material is provided in a range of up to about 25% of the weight of the whole tablet". The language is unclear regarding to the relationship between the granule and the extra granule material. Further clarification is suggested. Although the claims are interpreted in light

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of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Sunshine et al. US 4,980,375.

Sunshine teaches composition comprising mixture or ibuprofen and narcotic analgesic (columns 7-8).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnold US 4,587,252.

Arnold teaches compressed tablet formulation comprising combination of ibuprofen and narcotic analgesic (columns 2-3, and examples).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al., in view of Arnold US 4,587,252.

Sunshine and Arnold are relied upon for the reasons stated above. In the case the applicant can overcome the above 102(b) rejections, the examiner relies on the following 103(a) rejection. It would have been obvious for one of ordinary skill in the art to combine the teachings of Sunshine in view of Arnold with the expectation of at least similar result to the claimed invention, because the references teach the advantageous results in the use of ibuprofen and narcotic analgesic in a single mixture/phase.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elger et al. US 4,844,907.

Elger teaches tablet composition comprising combination ibuprofen and narcotic analgesic (abstract and examples). Elger teaches tablet composition can be made by wet granulating the active ingredients and excipients, including microcrystalline cellulose, starch, binder, glidants, anti-adherents, and disintegrants (columns 3-5). Elger does not teach the amounts of actives, excipients and relative proportions of the granule and extra granule material. However, it is the position of the examiner that no criticality is seen in the particular limitations since the prior art obtains the same result desired by the applicant, e.g., compressed tablet having good stability, disintegration times and dissolution rates. Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation determine suitable amounts of

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actives and excipients to obtain at least similar result, because Elger teaches the advantageous results in using the same ingredients.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elger et al., and Sunshine et al.

Elger and Sunshine are relied upon for the reasons stated above. It is the position of the examiner the skilled artisan would have been motivated to combine the teachings of Elger and Sunshine to obtain the claimed invention, because the references teach the advantageous results in the use of ibuprofen and narcotic analgesic. The expected result would be compressed tablet of ibuprofen and narcotic analgesic having good stability, disintegration times and dissolution rates.

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Baker et al. is cited as being of interest for the teaching of tablet formulation comprising ibuprofen and narcotic analgesic.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600